CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

REENGINEERING

YEAR 1 ACCOMPLISHMENTS
&
FUTURE PLANS

Organizational Transformation

JANUARY 1997 - DECEMBER 1997

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PREFACE

As the Czars of the Reengineering (RE) effort, we are pleased to provide this report of Year 1 Accomplishments of the Center's twelve RE teams. We are genuinely proud of how quickly and how well the Center has been able to handle organizational transformation in response to Dr. Burlington's charge twelve months ago. Remarkable progress has been made; in fact, many RE ideas are now Center policy, while other RE projects are expected to be piloted soon.

This report is divided into 4 sections:

1. Retrospective -- a historical record of the last year

2. Team reports -- information collected from each team leader by our interview team (Gary Blanken, Nancy Wynne and Patricia Bianchi)

3. Graphic information about some of the key pilots

4. Names of all team leaders and members, to acknowledge their contributions

We think you will be impressed by this record of the creativity of the ideas presented, the scope of the projects, and the willingness of our employees to "think outside of the box." Our deepest thanks go to the team leaders, the team members, their supervisors and all Center staff who offered their ideas, or were willing to test new ways of doing things.

Philip J. Frappaolo
Project Czar

Kimber C. Richter
Project Czar

RETROSPECTIVE

RENGINEERING RETROSPECTIVE

Still Committed to Reengineering

Over the past year we have committed ourselves to organizational transformation as a means to reengineer (RE) our work processes. We originally asked 10 teams to look for ways to improve the way we do business and in some cases to find ways to increase the effectiveness of our programs. Our goal was to focus Center resources on high-risk, high-impact products or work areas. Dr. Burlington challenged each team to think in bold terms and to pilot new ideas so that we could recognize inefficiencies, make appropriate corrections, and then move on. Using a six-stage approach, each team determined its customers, analyzed the current procedure, mapped an ideal process, redefined the process, developed a change management plan, and then implemented the RE effort. As of January31, 1998, six teams -- PDP, 515(b), 510 (k), Standards, Recalls and Regulations -- are being closed out since their ideas have been accepted by the Center and their pilots have proven successful. Full implementation of these ideas is now being turned over to line managers and employees in the Center's Offices as these new processes become Center-wide policy.

When the FDA Modernization Act (FDAMA) was passed, there was some concern that our Reengineering effort would be abandoned. Fortunately, many RE initiatives anticipated the new law and there were many aspects of the legislation that substantially advanced our RE efforts. For instance, Section 204 stipulates that FDA can recognize and use standards in its review process. Also, some of the Reengineering time frames have been replaced by tight statutory timelines. RE and FDAMA reinforce each other and both will be pursued in a coordinated fashion.

Consensus Building

Although part the Reengineering process was driven in part by shrinking budgets and the increasing complexity of devices, the major reason for Reengineering is good management. It makes good sense to periodically review our work to ensure that the most important things are getting done. In essence, RE is directed toward expending our resources where they are likely to have the greatest effect on public health.

As we took a fresh look at our essential program areas, we enlisted the support of our employees -- as well as medical device attorneys, health professionals, and industry representatives. We used a variety of techniques to gain input: all-hands meetings, focus group interviews, teleconferences, and talks with trade associations and congressional staff. In March 1997, Dr. Burlington issued a report to the Medical Device Community entitled "Increasing the Effectiveness of FDA's Medical Device Program: A Risk-Based Approach to Administrative Reform." In August 1997, he sent a progress report titled "New Directions in Medical Devices" to the Medical Device Community and all CDRH staff. In October 1997, the PDP team held a workshop cosponsored by HIMA to get important input from industry and health professionals before finalizing its comprehensive outline of the PDP process. Three teams effectively used the Internet and CenterNet to reach internal as well as external audiences; for example, the 510(k) Paradigm was made available via the World Wide Web for public comment.

Within the Center, we used the Organizational Transformation newsletter (OT News) to communicate vital messages. In May 1997, team leaders presented their proposals to the Center's senior managers and at a special meeting the RE Czars and steering committee presented an overall business plan based on this information. In partial response to employees' requests for information on how Reengineering was

specifically going to affect them, charts on workload impact and specific initiatives or pilots were developed and published in the August 1997 issue of OT News. We also used brown bag lunches, progress-report meetings, and issue-resolution meetings with line managers to communicate issues and resolve problems or overcome obstacles. Since many of the initiatives deal with pre-market issues, ODE took an active role in getting their reviewers involved in the new processes; in fact, several internal focus groups were used to discuss the new 510 (k) Paradigm, the PDP process, and the use of standards in product review.

In November 1997, at an all-day meeting on implementation of RE initiatives, senior managers discussed four questions: (1) What issues need to be addressed first, (2) How should we redirect and train staff to do new things, (3) How should we implement goals and evaluate success, and (4) How should we cope with existing workload and process change.

Before the end of the year, three additional areas for reengineering were added: Premarket Application (PMA), Administrative Processes, and Radiological Health Programs. The charge to the last of these groups is to see how we can minimize the effect of declining resources and loss of expertise on the regulation of diagnostic and electronic radiation-producing products and then coordinate these efforts Center-wide.

Accomplishments

The Regulations Team completed their initial work quickly. By the spring they had streamlined the regulations process (emphasizing early consensus on the concept of the regulation as the key to timely publication of regulations) and had already turned their attention to the eight regulations proposed by the other teams. Some of these regulations became successful pilots. Other successes followed, including: discontinuing the pre-clearance inspections program for Class I & II devices, triaging MDR reports when entered into the system (Code Blue), developing a PDP process, establishing summary reporting of adverse actions, doubling the number of MDRs being autoscreened, eliminating duplicative inspections of contract sterilizers, classifying Class II and III recalls in the District Offices, procuring and maintaining a standards database, approving 3 preamendment PMAs in 180 days using a streamlined process, and implementing a real-time review of product supplement applications. Also, as a result of Reengineering, we inventoried our administrative processes and requested and received delegations of authority appropriate to expedite clearance processes.

The new legislation gave a boost to the 510(k) team's efforts by codifying the use of standards in reviewing 510(k)s. And even though FDAMA provided a slightly different approach to classification of devices than envisioned by the 510(k) team, the effort to comply with the statute allowed us to identify 189 Class I and 62 Class II devices to be exempted from the 510(k) process and 52 Class I devices that will be reserved for 510(k) review (based on risk). This is expected to reduce the number of applications submitted by about 650 per year. PMA Reengineering and FDAMA also have much in common. In fact, some projects are advancing together. According to PMAT's team leaders, the description of the team's new PMA process, including modular review and the PMA shell, is being completed at the same time as the SOPs for collaboration meetings and interactive review are being finalized to meet the statutory deadlines.

Internet access is available for the PDP team and the GMP team (http://www.fda.gov/cdrh/pdp/pdp.html or /gmp/gmp.html) and Reengineering information can be found at http://www.fda.gov/cdrh/reengine.html. We are also getting inquiries from other Centers about our successes -- CBER has asked for a copy of our new

regulations handbook, and other Centers as well as the field are interested in gaining access to our Standards Database. Valuable information can also be found on CenterNet (aka Intranet).

What's Coming Next

During 1998, you can expect more news from the following teams: Hazard Benefit, Information Dissemination, PMAT, and our newest team, Radiological Health. On the administrative front we can expect information from the CDRH focus groups that gathered information from providers and users of administrative services. Also, look for news on a new inspection program to comply with the quality system regulation. The GMP team will concentrate on three areas: Quality Systems Inspections, Quality Systems Control Points including concepts from the Hazard Analysis and Critical Control Points (HACCP) program, and Quality Systems Training.

As implementation of new ideas takes place, activity will continue on some RE efforts even though the teams have disbanded. For example, as an expansion of its original mandate, the 515(b) team is currently preparing the necessary paperwork to call for PMAs for several disused preamendment Class III devices, and to propose the mass reclassification of other preamendment devices. These proposed rules are expected to be published soon. As this project continues, action will be taken by the Divisions to review PMAs and finalize reclassification decisions. In addition, educational efforts with industry and our own staff will continue until all participants understand and use the new streamlined processes. For example, the 510(k) team is considering a workshop in the spring to encourage sponsors to submit special or abbreviated 510(k)s.

Training

In support of the Reengineering effort, Staff College provided a number of training opportunities. A major effort was to develop workshops designed specifically for CDRH managers, supervisors, and team leaders to help them understand good practices for managing change during the Center's transformation. Similar workshops were provided to all employees on a voluntary basis.

Staff College also helped develop training for CDRH staff on high-priority provisions of the FDA Modernization Act and process changes resulting from premarket Reengineering. The three training modules included: (1) 510(k) provisions of FDA Modernization and the New Paradigm, (2) PMA/IDE high-priority provisions of FDA Modernization, and (3) PMA/IDE reengineering. The Standards team also worked with the studio to produce a training video on the use of the Standards Database; as of the end of January, over 600 employees had viewed the video.

Measures of Success

To determine the success of RE efforts, we will need to measure the changes that have occurred. If manufacturers don't submit special 510(k)s or abbreviated 510(k)s, for example, review times will not have improved. If -- on the other hand -- manufacturers use these new options, we will see the desired effect on review times. Overall, we will be looking to see if our Reengineering efforts have allowed us to shift resources to higher priority areas. Implementing these new processes should allow us to devote:

- **more time** to PMAs, IDEs, guidance development, consultation with industry, high priority standards development, use of standards in application review, high risk GMP inspections, and Class I recalls, and

- **less time** to Class I 510(k)s, modification of existing 510(k)s, low priority standards, low risk GMP inspections, redacting 510(k)s, data entry for low risk MDRs, Class II and III Recalls, and preamendments products no longer in use.

We will use numbers of documents and tracking of premarket submission review times to assess success -- OSM's Division of Information Technology Management has modified various databases so that progress can be tracked. The Center time-reporting system will also keep track of changes in work distribution.

Summary

We have accomplished much in a short time, due to the efforts of the RE teams and their colleagues who carried additional workload while new ideas were being tested. We owe them all a vote of thanks. As a result of their efforts we now have a new Standards Database, a new way to assess risk and prioritize work, new ways of dealing with pre-market review, new management reports for post-market decisions, streamlined processes for getting regulations published, and savings in compliance workloads. More good ideas are waiting to be implemented.

Throughout this process we have not had the luxury of implementing these changes in a leisurely way. We have moved quickly, asking staff to be creative and to test their ideas in pilots. Since many of these pilots have been accepted and are being implemented Center-wide, we need everyone's help and involvement in making organizational transformation a reality. Everyone needs to lend creativity and constructive criticism to the implementation process so that obstacles can be overcome and policy changes can be made.

TEAM REPORTS

In this section, you will find more detailed information about CDRH's *Reengineering Year 1 Accomplishments and Future Plans*. There is a page for each team that details its original goal, its accomplishments to date, the criteria it will use to measure the success of its pilots, the current status of the pilots still in progress, and future plans for pilots and for the team itself. Some teams have also provided a listing of obstacles that will have to be overcome before the full benefit of their pilots can be realized.

510(k) Team

Goal: To dramatically increase efficiency, bring safe and effective devices to market in an expedient manner, and maximize the contribution of Agency resources to public health and safety. A New 510(k) Paradigm proposes to virtually eliminate Class I 510(k)s and provide streamlined alternative review paths for most device modifications and for devices that conform to FDA-recognized standards or FDA guidance documents.

Accomplishments

- Issued a Federal Register notice requesting public comment on the draft document entitled "A New 510(k) Paradigm".
- Exempted certain convenience kits from the 510(k) process, and will issue a regulation to codify this practice.
- Discontinued the Pre-clearance GMP inspection program for Class I and Class II devices.
- Because of FDAMA, the team abandoned the idea of reclassifying Class I devices to Class II. Instead, following the FDAMA guidelines, ODE identified 62 Class II and an additional 189 Class I devices that -- based on risk -- will be exempt from the 510(k) process, and 52 Class I devices that will be reserved for the 510(k) process.

Measures of Success: The team will compare 510(k) submission rates before and after the 510(k) exemptions to estimate the impact of 510(k) exemptions. Measurement will also rely on time reporting and internal tracking systems to determine how much time is saved and where it is saved by the alternative review paths. Measurement may be difficult because numerous changes are occurring simultaneously and the receipt of 510(k) applications is declining.

Current Status: Progress continues in finalizing and implementing the New Paradigm -- modifications are being made based on comments received, and the final Paradigm should be issued by 3/20/98. Listings of Class I and Class II devices that are exempt from 510(k) were published in the *Federal Register*. A key component in abbreviated 510(k)s is the use of Standards; an initial listing of recognized Standards was made publicly available on 2/19/98. A Center working group is currently developing SOPs to implement the Paradigm within ODE's review Divisions.

Future Initiatives: Education, both inside and outside the Center, will be one of the team's biggest efforts in FY 98, because of FDAMA timelines. Guidance on General vs. Specific Intended Uses will also be developed.

Future of the team: The team is completing its primary RE work. The implementation phase has begun and primary responsibility for the RE efforts is shifting to Center staff within ODE.

Messages: Congress changed the rules -- placing a lot of emphasis on Standards. Key provisions of FDAMA dovetail with the team's RE efforts, thus strengthening the basis for implementing these changes.

RECALL TEAM

Goal: Reduce the number of CDRH FTEs used for recalls by delegating the lead for classification of Class II and III recalls to the District Recall Coordinators and retaining Center review for Class I Recalls.

Accomplishments:

- Class I Recall Authority was delegated to CDRH in September 1997.
- Six District Offices successfully piloted the process to determine if District Recall Coordinators could interactively classify Class II and III Recalls using an automated Health Hazard Evaluation (HHE) Precedent File (located on the CDRH CenterNet).
- Based on feedback, the team modified the criteria for recall reclassification and made information on CenterNet more user friendly (e.g., help screen).

Current Status: Eight additional District Offices have expressed an interest in participating in the pilot. Additional participants will be phased into the program at a rate of two per month. This will allow OC time to train the Recall Coordinators to make precedent decisions and use the CenterNet.

Measures of Success: Several measures are being considered, such as: 1) the number of District Offices adopting the recall classification system (indicating acceptance and use), 2) the number of Class II or III Recalls classified by the District Offices without being sent to OC, and 3) the decrease in CDRH FTEs performing recall work (as measured by time reporting).

Future Initiatives: Prior to full implementation, all District Offices will have a chance to use the pilot process. Further enhancements include the possible creation of a list (representing 25 percent of all devices) that could be used to classify recalls on the basis of historical precedent (this would incorporate HHE). The team also hopes to provide device firms access to the HHE database via the Internet so they can do their own analyses of Class II and III Recall precedents.

Future of the team: The original team disbanded shortly after the pilot study was initiated. An implementation team provides current direction for the continuing pilot and for maintenance of the precedent recall database.

Obstacles:

- CDRH needs to provide the field offices with reliable access to CenterNet.
- CDRH needs to convert the existing recall system, which utilizes Model 204, to ORACLE.
- Total automation may have been too ambitious; some Districts have experienced problems filling out the classification forms on-line.

Messages: Substantial resource savings can be realized by having the District Offices classify Class II and III Recalls (16 FTEs in headquarters), and firms will have faster classification decisions. This also presents the opportunity for a totally electronic recall system.

REGULATIONS TEAM

Goal: Streamline the regulations development process to improve the quality and timeliness of regulations.

Accomplishments:

- The Center has published two regulations under the team's streamlined process: 510(k) Class II Exemptions and the 510(k) Class I Exemptions.
- The process is being applied to other regulations, including: Glove Powder, Talc, 510(k)/FOI, Preamendments Reclassification, Effective Date of Requirement for PMA (3 Devices), Amendments to Diagnostic X-Ray Standards, and Menstrual Tampons.
- The team developed a regulation note-book (how-to manual) and provided training to the Senior Champions (regulation managers) on the streamlined process.
- In addition, the team developed Phase I training (overview of the process intended for a general audience), and presented it to staff in October 1997 and January 1998. Phase II training (in-depth training for regulation writers) will take place in Spring 1998, and will provide instructions for developing a concept paper, preparing a timeline, and writing the preamble and related regulatory sections.

Measures of Success: Proposal is to measure the length of time to get a regulation through the Center to see if the new process is faster than the old one. Since regulations vary in complexity, another measure might be the effectiveness of early communication among Center and Agency staffs in getting a quality product out in a timely manner.

Current Status: The regulations development team is currently working with the seven Senior Champions (for the regulations listed above). The team has purchased Chief Legal Officer software to track documents throughout the process.

Future Initiatives: A three-person team will continue to work with Senior Champions and provide assistance when necessary. They also plan to describe for Dr. Burlington the major obstacles to the regulations process outside of the Center's control (e.g., OMB list) and make recommendations for resolution of these problems. The team will also continue to monitor training needs for CDRH, and deliver training as needed.

Future Of The Team: To continue to work with the Senior Champions and other RE teams.

Obstacles: The major obstacle is making sure that the Senior Champions and the teams are following the new 5-Step Process.

PMA TEAM

Goal: To develop an IDE/PMA process that focuses resources on high-impact and high-risk products and produces smart, fast, and fair review decisions.

Accomplishments:

- The PMA Team developed a seamless model IDE/PMA process and pilot programs to provide efficient, timely, and fair PMA decisions. Using extensive input from all stakeholder groups, the new model creates early meetings with industry to identify data needs (the PMA "shell"), and resolves issues much earlier through a "modular review" process. By targeting decisions in 180 review days, the managed process eliminates unnecessary re-review of data and focuses resources on high-impact and high-risk devices by providing different review tracks: expedited, standard and streamlined.
- A pilot has begun in DCLD for a streamlined-review track for PMAs of devices that are well understood and have established criteria.
- A system -- developed as a joint project between the team and HIMA -- was devised to provide more predictability and consistency in determining when a supplement or report is needed for modification of a PMA device.
- Also, working with the Grassroots Premarket Subcommittee and the GMP Reengineering Team, a system was developed to ensure the best use of inspection resources for PMA products.
- To maximize efficiency, procedures for streamlining PMA sign-off were addressed and delegation options were expanded.
- Procedures were also created to improve the efficiency of development and use of the PMA Summary of Safety and Effectiveness Data as a project management tool.
- A pilot continues in the Dental Branch to develop tools for PMA project managers as additional project management options are developed. An IDE/PMA "Toolbox" web page is being developed to provide all stakeholders with ready access to relevant guidelines, procedures, and examples that facilitate the IDE/PMA process.
- Two pilots were initiated for product labeling across ODE. One established SOPs for review and closure on final draft labeling, including an interactive meeting with the sponsor. The other eliminated re-review of final printed labeling where it is either the same as the approved draft labeling or contains only minor changes.
- Implemented shared access to PMA inspection database information between ODE and OC. This access speeds communications and allows identification and earlier resolution of inspection issues.

Measures of Success: Evaluation criteria depend upon the particular initiative or pilot. Where IDE/PMA review time frames require long-term follow up, intermediate measures need to be developed and used. Many changes (i.e., the modular review concept) are projected to save PMA review time and reviewer resources, along with savings to the sponsor resulting from fewer re-submissions and iterations. Comparisons will be made between modular reviews and traditional PMA review times. Also, measures such as the percent of applications completed within expected time frames can be applied to the new IDE/PMA review model, then compared to existing baseline data. Implementation of the FDA/HIMA flowchart should result in fewer supplements for device modifications. Other measures of success would include supervisory and reviewer assessments, use of time-reporting data to measure saved resources, and customer satisfaction.

Current Status: Implementation of the IDE/PMA review model development process is underway. Draft SOPs for modular review are being circulated for comment and industry input is being evaluated. Assessment of the Dental Branch Project Management Milestones Pilot is due March 31, 1998. The

PMA Continued

IDE/PMA "Toolbox" will be on hold until the project can be merged with the Device Advice project (an interactive Web-Site being piloted by OHIP that consolidates medical device information for both Agency and industry). DCLD sent letters to industry announcing availability of the pilot for streamlined in-vitro diagnostic PMA review. The PMA inspection project with the Grassroots Premarket Subcommittee will be pursued with the GMP Team, ODE, and OC to refine the proposal and obtain comment on the draft.

FDA/HIMA's PMA modification flowchart is ready for Agency and public comment. Redelegation of sign-off authority for some PMA products to Division directors has been approved effective March 18, 1998, and is expected to be published in the *Federal Register* soon. Final draft plans for Summaries of Safety & Effectiveness Data are due April 1998. Results of the pilot studies for the review of final draft labeling and re-review of final printed labeling will be assessed in April 1998. The PMA team is also closely coordinating its reengineering efforts with the initiatives required under the FDA Modernization Act (FDAMA).

Future Initiatives: The PMA team assembled a list of potential process improvements and is pursuing the highest priorities. There are no other additional major processes, but additional lower priority issues should eventually be addressed. One example would be the master files, which could be improved. Also, if additional resources are made available to the IDE/PMA program, enhanced IDE/PMA project management could improve review efficiency.

Future of the Team: After designing the new process, the original PMA team suspended routine meetings and has become an extended group to help operational Offices with the implementation process. On-going pilots and the new model will now be managed by implementation teams. The implementation group will be re-formed as needed to maintain progress on the initiatives.

Obstacles:

- Baseline data must be determined to measure the impact of reengineering changes.
- Resources (dollars and FTEs) are needed to reach target review times.
- Enhanced attention to PMA project management is needed to ensure target times are met.
- SOPs, regulations and guidance documents must be processed.
- Staff and Industry buy-in and training are necessary.

Messages: Reengineering of the IDE/PMA process will require considerable buy-in, new procedures, and training. It will complement changes required by FDAMA.

515(b) TEAM

Goal: To reduce the preamendment PMA workload by streamlining the 515(b) process and managing it more efficiently.

Accomplishments: The team had 4 major accomplishments:

- Developed a PC-based tracking system for Class III preamendment devices, and a process to handle new PMAs generated by calls for their submission
- Piloted 3 preamendment PMAs in DGRD under new procedures; they were approved within 180 days
- Drafted 3 proposed rules and one final rule calling for submission of PMAs for medical devices that have fallen into disuse
- Wrote a proposed rule to down-classify preamendment devices into Class II, along with a listing of Class II special controls.

Measures of Success: The team's initial efforts and pilots have been successful. Procedures developed for review of preamendment Class III devices will expedite their processing, as measured by the time required for a final decision. As the proposed regulations are finalized and the number of preamendment devices declines, the 515(b) program should eventually "put itself out of business."

Current Status: Development of the PC-based tracking system for Class III devices is continuing, along with implementation of procedures to manage submissions of future Class III preamendment device PMAs. The team is assisting the Hazard Benefit Team in validating their Hazard Categorization Questionnaire by using it during the mass reclassification decisions and calls for PMA decisions. The regulations for disused medical devices are undergoing final edits before they are finalized and published. The first draft of the proposed mass reclassification rule is being circulated for review.

Future Initiatives: The initiatives above will probably continue over the next 2 to 3 years. Two additional "calls for information" under Section 515(i) are planned during Spring and Summer 1998. The implementation team may need to respond to comments once proposed regulations are published. Training of ODE review staff and panel members in procedures for Class III preamendment PMAs will also be required. This training is extremely important, since failure to understand the process could result in a product being taken off the market.

Future of the team: The original reengineering team disbanded at the end of FY97, and an implementation team is managing ongoing activity. The team will continue training staff and tracking the proposed regulations. James Dillard is the designated Senior Champion for the regulations initiatives.

Obstacles: The implementation team will need to identify future members as current ones leave.

Messages: The lengthy, arduous processes for reclassifying or calling for PMAs for preamendment Class III Devices are being replaced with more streamlined approaches to reclassify or review PMAs for these devices.

PDP PROCESS TEAM

Goal: To develop an alternative to IDEs and PMAs that will reduce time to market and the expenditure of FDA resources while maintaining the safety and effectiveness of products. The team will use PDP provisions already in the law as a basis for providing early preclinical involvement by FDA and advisory panels to establish product review criteria, so that later conformance can be assessed more promptly.

Accomplishments:

- The team developed a process for PDP submission to include: PDP summaries, PDPs, progress reports, and notices of completion. Under this process, FDA makes a determination on whether PDP is appropriate, based on the sponsor's summary. The company then submits a PDP describing the device, proposed studies, and acceptable results. When the studies are completed, the sponsor submits a notice of completion.
- The team developed several process documents: summary formats, a comprehensive outline, a policy for dealing with product modification during the PDP process, and a progress report submission format. These documents are published on the Internet and the CenterNet. As a result of the October 1997, workshop co-sponsored with HIMA, the PDP process is being fine-tuned and SOPs are being implemented. Design control and design verification are being integrated. Two PDPs have gone to Panel: Cardiovascular and OB/GYN; agreement on protocols is expected by mid-March. Eleven other PDPs are in-house.
- The team developed a proactive and interactive approach to working with industry. From its inception, this team had industry input as a goal. Many of its members are from industry and frequent meetings were held with industry, such as the October workshop mentioned above where over 230 industry and academic representatives met to discuss the PDP process. As a result of significant dialogues among manufacturers, academics and an expanded FDA staff, the "Comprehensive Outline" was simplified, and changes were made to Good Manufacturing Practices/Quarterly Systems Requirements and PDP supplement submission information.

Measures of Success: After a few more PDPs are processed, the team plans to meet with staff to get their feedback. In the meantime, ODE staff is tracking the in-house PDPs via their "purple" jackets and special flags entered into the established tracking system.

Current Status: The team is still fine-tuning their processing documents as well as considering additional products for the Pilot. Further training is planned to educate and get buy-in. The team is also working with OST to integrate the PDP process with design-control requirements.

Future Initiatives: The team hopes to have implementation members in each Division, establishing a plan to assess the PDP program, and setting up meetings to get reviewer "buy-in."

Future of the team: The PDP reengineering process has matured to the point where the Center has integrated the PDP into its arsenal of product-approval mechanisms. As experience is gathered with the PDP process over the next 2 years, regulations will likely be written.

Obstacles: No real obstacles are foreseen at this time; we just need to stay focused on the project and resolve necessary changes as PDPs are processed.

STANDARDS TEAM

Goal: To create a process to provide consensus Standards that will meet Center needs, save resources when used in product review or other processes, and maintain public health protection.

Accomplishments:

- Completed a successful pilot to review Standards and their utility to the premarket review process. The first list of 174 Standards CDRH recognizes was published 2/19/98 on Internet and 2/25/98 in the *Federal Register*. This implements Sect. 204 of the FDA Modernization Act, which allows manufacturers to voluntarily submit, as part of a premarket application, a declaration of conformity to a recognized Standard in lieu of data and information addressed by the recognized Standard.
- Purchased and installed a database for Standards which is now on-line throughout the Center. Additional software was procured on other Standards, and these Standards are now available to Center personnel via CD ROM in the CDRH Library. Mandatory Standards training was conducted for all employees in the Center. Over 500 queries were made in the first month of use.
- Established thirteen Specialty Task Groups (STGs) (inter-office groups) to guide standards development and coordinate use of standards by device type.
- Worked with OST, ODE and OC to complete several documents:
  - Guidance on the Recognition and Use of Consensus Standards
  - *Federal Register:* announcing guidance on the use of Standards, listing CDRH's first recognized Standards, and stating the policy on recognizing Standards
  - SOPs for recognition of Standards
  - Supplemental data sheets which provide additional information on each recognized Standard
  - Answers to frequently asked questions

Measures of Success: The impact of Standards will be reflected in premarket submission review times. The number of abbreviated 510(k)s submitted will also indicate the extent of standards use. The number of additional standards recognized will reflect the success of the STGs. The 510(k) database will be used to track devices that claim conformance to standards, and the team may use that information to compare these to other applications that do not declare conformance. A questionnaire may be used later to get the reviewers' comments about the use and value of Standards.

Current Status: Thirteen Specialty Task Groups are working to identify further Standards for recognition, to establish center consensus on Standards issues, and to identify needed Standards development projects.

Future Initiatives:

- Expand the Standards database and promote its use throughout FDA.
- Implement postmarket monitoring of information supporting the declaration of conformity through random checks.
- Hold roundtable discussions on Standards for Software Type Devices.
- Continue the education phase of the program.
- Continue efforts on harmonization and the Mutual Recognition Agreement with EU to solidify the use of Standards in the review process.

Future of the team: The initial RE work of this team is done and the team has disbanded. OST is now leading the implementation efforts on Standards. The Specialty Task Groups are implementing the changes and will continue to communicate and work for consensus on Standards use within the Center, Field and Labs.

Obstacles: Acquiring Standards that are relevant to the medical device area. The Center will need approximately $100,000 yearly to update the Standards database.

ADMINISTRATIVE PROCESSES TEAM

Initial Goal: To inventory the status of recently completed and ongoing efforts to improve or reengineer the Center's administrative processes, including measures of resource savings or other beneficial impacts. To obtain further input from the Center's employees that helps focus on other candidates for administrative process reengineering. To undertake those efforts that could effect real resource savings, improve administrative services, reduce cycle time, reduce paperwork, or generally support organizational transformation.

Accomplishments:

- Recent and ongoing initiatives for administrative processes were inventoried.
- An update on recent delegations of authority was in the Jan/Feb OT News.
- An update on additional initiatives is planned for the March/April issue.
- Held four focus-group meetings in January to explore which administrative processes may need attention from the perspective of Center users and providers of administrative services.

Measures of Success: Staff satisfaction with the way administrative processes are communicated and implemented (after reengineering) would be a useful measure of success.

Future Initiatives: A proposal for enhanced communications on recently implemented, new, or unclear processes with (and among) users and providers is being developed and will be presented for consideration in Spring 1998. A second proposal to communicate with FDA on unresolved issues involving processes under FDA's authority will be presented at the same time.

Future of the team: Depends on the decisions made on the proposals noted above.

Obstacles: Do the proposals have enough merit to warrant the increased administrative staff effort necessary to pursue them?

MDR TEAM

Goal: To reduce the volume of paper, improve the quality of data, and enhance the effectiveness of adverse event reporting at a lower cost. Steps will be taken to spend fewer resources entering individual reports and to use more resources developing streamlined reporting systems that can yield higher-quality information using innovative surveillance methodologies.

Accomplishments:

- The team developed a successful procedure, known as Code Blue, to identify reports that should be reviewed immediately. The team plans monthly distribution of this Code Blue report in the future; it is currently being sent to Dr. Burlington, Dr. Jacobson, and CDRH Office Directors each week in order to provide an immediate view of potentially high-risk issues.
- In the first phase of summary reporting, the Center offered an exemption to the manufacturers of the 12 devices that were currently being autoscreened. This exemption would allow them to report quarterly in a summary fashion rather than submit individual reports. Approximately 25 manufacturers requested this exemption -- it is expected this will decrease the number of individual reports received by approximately 20,000 per year. A second group of devices (the majority of which are currently autoscreened) will be moved to summary reporting after validation of the reporting format and analysis procedure being used.
- Facility recruitment for Sentinel Reporting Pilot (a preferred mechanism for user-facility reporting) was completed 9/30/97; orientation workshops were held in October 1997; and a Newsletter was issued that is proving to be a valuable source of feedback to clinical facilities. The initiative to improve coding is underway with funding to the existing contract, and may result in a coding manual.

Measures of Success: The analysis of the Sentinel Reporting pilot will be both qualitative and quantitative, and the results will be key in designing the national system. Evaluation of summary data includes analyzing the quality of reports, particularly in regard to coding, and doing a quantitative assessment of how these data compare to the aggregate analysis of individual reports over the past year (i.e., are the same types of events being seen, and are the numbers fairly consistent).

Current Status: The Sentinel Reporting project is in its data collection phase until 10/98; the final report is due 1/99. Two planning workshops are scheduled for Spring/Summer 1998. Process improvement for MDR analysis includes: (1) development of SOPs by Spring 1998, and (2) exploration of issues such as how to apply epidemiologic principles to data. In our efforts to improve coding, a procurement has been completed, and meetings are being held with the contractor to gather information on how to proceed.

Future Initiatives: International harmonization of MDR issues will be explored.

Future of the team: The original RE team has disbanded -- sub-teams are implementing the changed processes.

Obstacles: To make Sentinel Reporting a national system, money is needed for contract support. Also -- in order for this to be a quality system -- education, training, intensive collaboration with user facilities and the clinical community, a newsletter, and feedback to users are needed.

GMP TEAM

Goal: To change the Good Manufacturing Practices inspection process to eliminate duplication in review, ensure compliance of high-risk products, and be more responsive to customers. This will be accomplished by working with the Field and others to develop a risk-based inspection strategy that will redirect resources into higher-risk product inspections and streamline the way they are conducted.

Accomplishments: GMP Reengineering involves four projects at this time. Two of the four projects have been implemented.

- On September 11, 1997, CDRH and the Field initiated a change to eliminate duplicative inspections done at contract sterilizers who perform work for PMA applicants.
- In January, 1998, CDRH started a 6-month pilot with 6 Districts, which should reduce Headquarters involvement with post-inspection NAI and VAI paperwork done at the conclusion of some foreign inspections.

Two other projects are underway. They are explained below under "Current Status".

Measures of Success: The contract sterilizer project was started without a pilot because the benefits were obvious. Some data are being collected by the field to demonstrate its effectiveness. The benefit of the post-inspection paperwork project for foreign inspections is being measured by the pilot Districts.

Current Status: Two projects are ongoing. The first of these is a project to modify the inspection technique used by the Districts to conduct Quality Systems (GMP) inspections of manufacturing firms. The second is a pilot to develop a Hazard Analysis and Critical Control Points (HACCP)-type program for certain medical devices. Both of these projects are part of the team's risk-based Quality Systems Reengineering effort.

The inspection technique project, called the Quality Systems Inspections Project, was initiated in November 1997, with an industry meeting. A second meeting was held in January 1998, and the team expects to provide formal input to CDRH in late April 1998. Soon afterward the team will evaluate the proposal and begin follow-up activities to move toward implementation. The goal of this project is to develop a tool for conducting inspections in a systems-oriented way under the Quality Systems Regulation, and at the same time consider harmonization strategies designed to explore the European auditing systems currently being used under the Mutual Recognition Agreement. A second goal is to complete inspections faster and in a more focused manner.

In February, the HACCP project was formally assigned to a sub-team leader, and the new team will develop and implement a pilot project with a small number of manufacturers that use a HACCP-type program to ensure quality. Most likely this will involve manufacturers of class I and/or class II devices. Another term used in describing this project is Quality Systems Control Points (QSCP), which is synonymous with HACCP, but would only involve devices.

Future initiatives: A training project is envisioned to cover the new inspection programs described above.

Future of the Team: Two sub-teams are in existence. Management of the pilots already underway will be handled by the former Reengineering team leader.

Obstacles: The only serious obstacle is obtaining the funding for the HACCP effort, and for travel and training relating to the new inspection program.

INFORMATION DISSEMINATION TEAM

Goal: To provide accurate, complete, current, and consistent information to our customers and staff in a timely, efficient, and economical manner. To establish a CDRH "information desk", an electronic means of communicating with the public, and less burdensome methods of registration and listing, and to reduce the 510(k) workload within the Center's FOI staff.

Accomplishments

- Completed plans for a pilot study to demonstrate the usefulness of a CDRH "information desk" as a means for the public to obtain information from the Center
- Completed initial interviews of FDA registration and listing staff, as a first step in designing a more useful and less burdensome registration and listing system
- Prepared a draft 510(k) redaction regulation to shift the burden of redacting 510(k)s from FDA to applicants.

Measures of Success: For the information desk, the team will assess customer satisfaction based on user feedback. Communications using list-server technology will be evaluated by obtaining feedback from list-server subscribers and by determining the number and composition of subscribers. Procedures for evaluating modifications to the Center's registration and listing system will be developed in the future. Time reporting data will be used to measure the impact of the redaction regulation on 510(k) time spent by the Center to respond to FOI requests for 510(k)s..

Current Status: Resource requirements for the information desk pilot study are under review by Senior Staff. The effort has not yet been staffed, and will require three persons on 90-120 day details. A sub-team is continuing to explore various approaches to using electronic channels to improve communication. Information is being collected from industry, beginning in February 1998, on improving the registration and listing system. The proposal for a pilot test to examine the feasibility of collecting registration and listing information through the Internet has been approved. A draft of the proposed rule on 510(k) redaction will be sent on for review during Spring/Summer 1998.

Future Initiatives: Continue to identify efficient methods of communicating with the public, industry, device user facilities and health care professionals. Overhaul the registration and listing process.

Future of the team: Subcommittees were formed to work on the four major initiatives: (1) Information Desk, headed by Neil Goldstein, (2) Electronic Communication, headed by Bonnie Markovitz, (3) Registration and Listing reengineering, headed by Bonnie Malkin, and (4) Pilot of WWW-based Registration and Listing, headed by Michelle Hudson. They will continue to develop these areas until pilot studies are completed and decisions are made on which initiatives to adopt permanently.

Obstacles: Details must be established for staffing the information desk pilot. CDRH staff will need training on how to handle initial contacts for information. Any redesign of the registration and listing systems must be coordinated with affected Agency components and industry must be advised of any new approach; also, considerable resources would be required to complete this initiative.

Messages: Information dissemination is an ongoing process which always requires significant resources. New technologies may provide significant opportunities to streamline existing processes.

HAZARD BENEFIT TEAM

Goal: To develop more consistent measures of device hazards that can be used to help prioritize the Center's premarket, postmarket, and compliance activities.

Accomplishments: The team:

- Developed and completed initial testing of a hazard analysis questionnaire, which assigns devices to hazard risk categories. The 515(b) team used its mass reclassification list to help validate the questionnaire.
- Proposed a procedure for assigning devices and device groups to the appropriate level of MDR surveillance (e.g., summary reports, auto-screen).
- Proposed a method for use by OC to assign routine inspection frequency levels to individual devices based upon their hazard categorization.

Measures of Success: Extent to which hazard prioritization tools are utilized by Center staff to make product-hazard-based resource and program priority decisions.

Current Status: Work continues on the three initiatives: (1) The team is continuing to test its analysis questionnaire; (2) The team is working to incorporate its efforts into Standard operating procedures being developed by OSB for determining levels of MDR review; (3) The team is studying the assignment of routine inspection frequency levels to see how well it works.

Future Initiatives: Review the Canadian and European hazard categorization systems to determine their consistency with the Center's categorization system.

Future of the team: The team has accomplished much of its original goal. Several team members remain involved in testing the hazard analysis questionnaire and obtaining broader Center review and comment on its usefulness. The team will assist Center offices in incorporating hazard categorization concepts into their activities.

Obstacles: The hazard analysis questionnaire could be used to determine whether device reclassification is needed. However, even in the absence of formal reclassification, a hazard benefit assessment can be used to guide prioritization of products within the Center. Although the hazard benefit reengineering process has been met with some concern that it will dictate the resolution of complex issues, it is important to stress that the goal of the hazard categorization system is to standardize the decision-making process within the Center, rather than to automate it.

Messages: Hazard categorization has broad applicability to Center programs, for example, Premarket review, MDR, and Compliance.

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